Cellabs Product Profile

CHLAMYDIA CEL

INTENDED USE AND PRINCIPLE OF THE TEST

The Chlamydia Cel IF Test is a rapid *in vitro* direct immunofluorescence test for the detection and diagnosis of *Chlamydia trachomatis* organisms in patient specimens. The fluorescein-labelled mouse monoclonal antibody reagent binds specifically to *C. trachomatis* in the specimen.

CONTENTS OF THE KIT

The Chlamydia Cel range is available in a number of formats, including: 10 Test Demo (KC1 Demo), 50 Test (KC1), 200 Test Bulk, Positive Control Slide only, and Mounting Fluid only. Note that the Chlamydia Cel Reagent has been optimised for use with Cellabs *C. trachomatis* Positive Control Slide and Mounting Fluid.

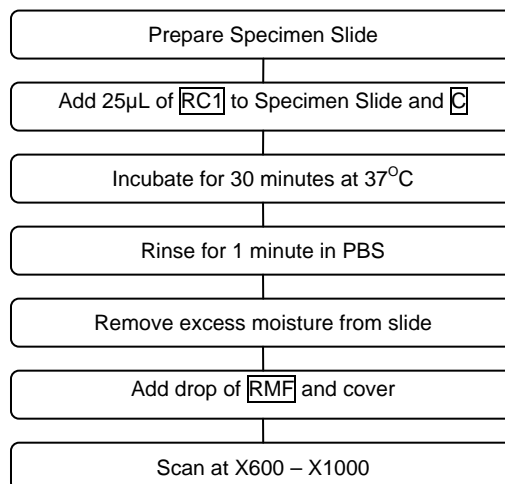|		KC1 Demo	KC1 Standard	Bulk
RC1	Chlamydia Cel Reagent	0.25mL	1.25mL	5mL
C	Positive Control Slide (Single Use only)	1	1	-
RMF	Mounting Fluid	2.5mL	2.5mL	-
	Tests	*10*	*50*	*200*

All components should be stored at 2-8°C, and are supplied ready for use. Expiry dates are clearly marked on each kit component and on the box and do not change once opened.

MATERIALS REQUIRED BUT NOT PROVIDED

- Microscope slides with 6-8mm diameter wells
- Methanol for specimen fixation
- Precision pipette for delivering 25µL
- Humid chamber
- Wash bath
- Phosphate buffered saline (PBS) for washing step

- Cover slips
- Non-fluorescing immersion oil
- Fluorescence microscope with filter system for FITC (maximum excitation wavelength 490nm, mean emission wavelength 530nm) and x600-x1000 magnification

DIAGRAM FOR USE

Use Cellabs Instructions for Use Insert contained in kit when performing test, and refer to Material Safety Data Sheet (MSDS) for further information.

```
        Prepare Specimen Slide
                 |
Add 25µL of RC1 to Specimen Slide and C
                 |
     Incubate for 30 minutes at 37°C
                 |
        Rinse for 1 minute in PBS
                 |
    Remove excess moisture from slide
                 |
        Add drop of RMF and cover
                 |
          Scan at X600 – X1000
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READING AND INTERPRETATION OF RESULTS AND DIAGNOSIS

C. trachomatis elementary bodies and reticulate bodies fluoresce bright apple green (with typical morphology) against a background of reddish/brown counterstained material. Results should be compared with the Positive Control Slide.

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PERFORMANCE DATA FOR CHLAMYDIA CEL

Sensitivity/Specificity

A	n = 184 clinical specimens (180 female cervical, 4 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 100% Specificity: 99.4%
B	n = 29 clinical specimens (6 female cervical, 23 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 95.8% Specificity: 100%
C	n = 200 clinical specimens (62 female cervical, 138 male urethral).. Chlamydia Cel versus a commercial ELISA.	Sensitivity: 100% Specificity: 100%
D	n = 200 clinical specimens (62 female cervical, 138 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 100% Specificity: 100%
E	n = 400 clinical specimens (332 female cervical, 68 male urethral). Chlamydia Cel versus coverslip culture.	Sensitivity: 100% Specificity: 99.5%
F	n = 270 clinical specimens (121 female cervical, 149 male urethral). Chlamydia Cel versus another commercial Chlamydia IFA.	Sensitivity: 100% Specificity: 100%
G	n = 315 clinical specimens. Chlamydia Cel versus primary culture.	Sensitivity: 100% Specificity: 100%

Repeatability & Reproducibility

5 identical antigen samples were tested by 3 different operators and there was 100% correlation in the results.

Cross reactivity

The Chlamydia Cel does not cross react with:

Beta haemolytic Streptococcus group B
Beta haemolytic Streptococcus group A
Lactobacillus acidophilus
Peptostreptococcus anaerobius
Proteus mirabilis
Escherichia coli
Streptococcus faecalis
Staphylococcus aureus

Pseudomonas aeruginosa
Staphylococcus epidermidis
Bacteriodes melaninogenicus
Actinomyces israelii
Gardnerella vaginalis
Neisseria gonorrhoeae
Candida albicans
Trichomonas vaginalis

For Ordering Assistance:

See Your Local Distributor:

OR

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